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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,477	12/31/2003	Philip P. Narini	CU-3513	9849

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EXAMINER

CRAIG, PAULA L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/750,477	Applicant(s) NARINI ET AL.	
	Examiner Paula L. Craig	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Claim 11 claims a sealing means including adhesive means for sealing off the collar around or against a body part.

Therefore, the adhesive means must be shown or the feature canceled from the claim.

No new matter should be entered.

2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The use of the trademark Velcro has been noted in this application on page 8, line 16, and in Claim 10. It should be accompanied by the generic terminology wherever it appears, such as "hook and loop fastener".
4. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "said end" in line 4 of the claim. Claims 10-11 recite the limitation "said collar" in line 2 of each claim. There is insufficient antecedent basis for these limitations in the claims. Claims 2-11 are rejected as being dependent on Claim 1.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,316,541 to Fischer.
9. For Claim 1, Fischer teaches a fluid containment device comprising a flexible bag body defining a containment space (reference numbers 12 and 15, Fig. 1 and col. 3, lines 22-28). The bag body includes walls and at least one opening (walls 25, 26, 27, and 28; incision in adhesive assembly 18; Figs. 1-4 and 12-13, col. 3, lines 27-35, and col. 5, lines 39-56). The opening includes a means for sealing off an end (col. 2, lines 8-12, and col. 5, lines 20-51). Means are provided for accessing through the bag body walls and into the containment space (access portal assembly 20 and gloves 16, Fig. 1, col. 3, lines 27-35, and col. 4, lines 63-67). Means are provided for inflating portions of the walls to provide rigidity and strength to the walls (support structure 14 and pocket 42, Figs. 1 and 8, col. 3, lines 42-67).
10. For Claim 3, Fischer teaches the bag body being comprised of at least two flexible membranes. See Figs. 1 and 8 and col. 3, lines 42-67.
11. For Claim 4, Fischer teaches the bag body including an inner membrane and an outer membrane disposed adjacent each other to form a double layered wall. See Fig. 8, col. 3, lines 42-67, and col. 6, lines 29-31.
12. For Claim 5, Fischer teaches the inflating portions defined by the space between the inner and outer membranes. See Fig. 8 and col. 3, lines 42-67.

13. For Claim 6, Fischer teaches the inflating portions comprising inflatable chambers extending between sealed locations where the outer and inner membranes are sealed together. See Fig. 8 and col. 3, lines 42-67.
14. For Claim 7, Fischer teaches the inflatable chambers including horizontal inflatable chambers and vertical inflatable chambers. See Figs. 1, 2, and 8.
15. For Claim 8, Fischer teaches the inflatable chambers being tubular in shape. See Figs. 1, 2, and 8.
16. For Claim 11, Fischer teaches the sealing means including adhesive means for sealing off a collar around or against a body part (see adhesive assembly 18 of Fischer, Figs. 1, 12, and 13, and col. 5, lines 20-51).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,316,541 to Fischer in view of U.S. Patent No. 5,312,385 to Greco.

20. For dependent Claims 2 and 10, Fischer teaches all the limitations of Claim 1, as described above in paragraph 9. For Claim 10, Fischer teaches a collar sealed off around or against a body part (see adhesive assembly 18 of Fischer, Figs. 1, 12, and 13, and col. 5, lines 20-51). This attaches the enclosure of Fischer firmly against the patient throughout the procedure (Fischer, col. 5, lines 35-38).

21. For Claim 2, Fischer does not expressly teach a means for draining fluids captured within the containment space. Greco teaches a fluid containment device having a drain, which allows drainage of fluids captured within the containment space (Greco, exit port 6 and plastic tube 7 of Fig. 1, and col. 5, lines 1-12). The drain allows drainage of contaminated irrigation material (Greco, col. 5, lines 1-12). It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the fluid containment device of Fischer to include a drain to allow drainage of contaminated irrigation material, as taught by Greco.

22. For Claim 10, Fischer does not teach the sealing means having means including Velcro male and female connectors (hook and loop fastener) for sealing off the collar around or against a body part. Greco teaches an end sealing means for sealing a collar around a body part; the end sealing means may be a strap of hook and loop fastener. See Greco, reference number 3, Fig. 1 and col. 4, lines 43-59. The end sealing means provides a substantially water-tight and non-leaking seal while irrigating a wound (Greco, col. 4, lines 16-19 and 33-59). It would have been obvious to one of ordinary

skill in the art to modify the device of Fischer to include hook and loop fasteners for sealing off a collar around a body part, as taught by Greco, to provide a substantially water-tight seal while irrigating a wound.

23. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,316,541 to Fischer in view of U.S. Patent No. 5,107,859 to Alcorn et al.

24. For dependent Claim 9, Fischer teaches all the limitations of Claim 3, as described above in paragraph 10. Fischer does not teach the membranes including an inner dimpled surface. The phrase "such that when said bag body collapses onto itself voids are formed between said bag walls forming drainage pathways for any entrapped fluids in said fluid containment device" is considered by the Examiner to be functional language of little patentable weight in an apparatus claim. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), and *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967).

25. For Claim 9, Alcorn teaches a bag for handling fluid runoff during surgical procedures having an inner dimpled surface. See Alcorn, Figs. 4, 4A, 5, and 7, and col. 4, line 65 to col. 5, line 55. The corrugated surface of foam support 12 of Alcorn is described as allowing the channeling of fluid to the drainage ports even if the sidewall of the bag collapses, as fluid will flow between the ridges (col. 5, lines 1-13). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the

device of Fischer to include an inner dimpled surface as taught by Alcorn, to allow the drainage of fluid even if the sidewall of the bag collapses.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 3,850,172 to Cazalis shows a gas-tight enclosure for a surgical operation, including an adhesive attachment to the patient. U.S. Patent Nos. 4,000,749 to Busco, 5,437,602 to Polyakov et al., and 6,461,290 to Reichman et al. show inflatable isolation devices for patients which include drains. U.S. Patent No. 6,217,507 to Bonvik shows an isolation unit having a framework of horizontal and vertical inflatable chambers. U.S. Patent No. 6,314,958 to Harroll et al. and U.S. Patent Application Publication No. US 2004/0045557 to Lee show medical drapes with an inflatable portion. U.S. Patent No. 4,602,773 to Craven, Jr. shows an extremity debridement trough. U.S. Patent Nos. 4,656,997 to Morales-George, 5,178,162 to Bose, 5,447,504 to Baker et al., 5,609,163 to Beard, and 6,083,209 to Marasco, Jr. show enclosures for irrigating during surgery or treatment. U.S. Patent Nos. 5,743,435 to Tomic, 5,970,979 to Christofel et al. and U.S. Patent Application Publication No. US 2002/0148857 A1 to Savage et al. show bags having inner surfaces with upstanding corrugations, bumps, or ribs which allow fluids to flow through.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571)272-5964. The examiner can normally be reached on 8:30AM-5:00PM M-F.

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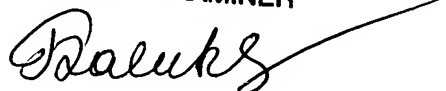
28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571)272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paula L Craig
Examiner
Art Unit 3761

PLC

TATYANA ZALUKAEVA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Zalukaeva', with a long horizontal flourish extending to the right.